

AMENDMENTS TO THE CLAIMS

1-36. (Canceled)

37. (Previously presented) A method of treating cancer comprising: administering to a patient a pharmaceutical composition comprising an effective amount of (a) heat killed whole cell *Mycobacterium w*, (b) sonicated *Mycobacterium w*, (c) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, and hexane, or (d) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase and pronase.

38. (Previously presented) The method of claim 37, wherein the method is for reducing the progression of cancer tissue.

39. (Previously presented) The method of claim 37, wherein the method is for increasing the efficacy of radiotherapy or chemotherapy in the treatment of cancer.

40. (Previously Presented) The method of claim 37, wherein the method is for reducing the side-effects of radiotherapy or chemotherapy.

41. (Previously Presented) The method of claim 40, wherein the side effects are hematological side effects.

42. (Previously presented) The method of claim 40, wherein the side effects are reduced to avoid interruption of chemotherapy.

43. (Previously Presented) The method of claim 40, wherein the side effects are leucopenia, thrombocytopenia, anaemia, nausea, vomiting or mucositis.

44. (Previously presented) The method of claim 37, wherein the *Mycobacterium w* is dead *Mycobacterium w*.

45. (Previously presented) The method of claim 44, wherein the *Mycobacterium w* has been killed by a physical method.

46. (Previously presented) The method of claim 45, wherein the physical method is the application of heat.

47. (Previously Presented) The method of claim 46, wherein the heat is applied by means of autoclaving.

48. (Previously presented) The method of claim 37, wherein the pharmaceutical composition comprises sonicated *Mycobacterium w*.

49. (Previously presented) The method of claim 37, wherein the pharmaceutical composition comprises *Mycobacterium w* obtained by extraction.

50. (Previously presented) The method of claim 49, wherein the *Mycobacterium w* is extracted with organic solvents.

51. (Previously presented) The method of claim 50, wherein the organic solvents are selected from the group consisting of chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea and hexane.

52. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises one or more adjuvants.

53. (Previously Presented) The method of claim 52, wherein the pharmaceutical composition further comprises a surfactant.

54. (Previously Presented) The method of claim 53, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate.

55. (Previously Presented) The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.4% by weight/volume of the pharmaceutical composition.

56. (Previously Presented) The method of claimer 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.1% by weight/volume of the pharmaceutical composition.

57. (Previously presented) The method of claim 37, wherein the *Mycobacterium w* is urease negative, does not hydrolyze polyoxyethylene (20) sorbitan monooleate , does not produce niacin, and provides a strong positive response to nitrate reduction tests.

58. (Previously presented) The method of claim 37, wherein the pharmaceutical composition is administered alone or in combination with other modes of therapy selected from radiotherapy and chemotherapy.

59. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by parenteral route.

60. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by intramuscular, subcutaneous or intradermal route.

61. (Previously presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising at least 10^5 *Mycobacterium w*.

62. (Previously presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising at least 10^7 *Mycobacterium w*.

63. (Previously presented) The method of claim 37, wherein the pharmaceutical composition is in a unit dosage form comprising from 10^8 to 10^{10} *Mycobacterium w*.

64. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises a preservative.

65. (Previously presented) The method of claim 37, wherein the cancer is a primary or a secondary metastatic lesion.

66. (Previously presented) A method of improving the quality of life in a patient suffering from cancer comprising: administering to a patient a pharmaceutical composition comprising an effective amount of (a) heat killed whole cell *Mycobacterium w* (b) sonicated *Mycobacterium w*, (c) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, and hexane, or (d) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase and pronase.

67. (Previously Presented) The method of claim 66, wherein the improvement in quality of life is obtained in the absence of other modes of treatment.

68. (Previously presented) The method of claim 66, wherein the improvement in quality of life is obtained with the addition of other modes of treatment selected from radiotherapy and chemotherapy.

69. (Previously presented) A method of amelioration of symptoms associated with cancer comprising: administering to a patient a pharmaceutical composition comprising an effective amount of (a) heat killed whole cell *Mycobacterium w*, (b) sonicated *Mycobacterium w*, (c) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea, and hexane, or (d) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase and pronase, wherein the symptoms associated with cancer are selected from pain, abnormal hemoglobin, cough, breathlessness, dysphagia, neutropenia, and irregular sleep.

70. (New) The method of treating cancer according to claim 37, wherein the pharmaceutical composition is administered by intradermally.

71. (New) The method of treating cancer according to claim 37, wherein the cancer is superficial bladder cancer, and the composition is administered intradermally over the deltoid region.

72. (New) The method of treating cancer according to claim 37, wherein the cancer is muscle invasive bladder cancer, and the composition is administered intradermally over the deltoid region.